

REMARKS**I. Status Of The Claims.**

Claims 1-28 are pending in the Application. This Response and Amendment cancels Claim 26 and amends Claims 1, 7, 12, 16-17, 19 and 27-28. Accordingly, Claims 1-25 and 27-28 are pending in the Application.

II. Claim Amendments.**Claims 1, 12, and 17.**

Claims 1, 12 and 17 have been amended to delete the recitation of “the lower surface” on line 22 of Claim 1, line 211 of Claim 12, and line 23 of Claim 17 and to correctly recite “the bottom surface. These amendments merely correct a typographical error and do not alter the scope of the claims or add new matter. Entry of these amendments is respectfully requested.

Claim 7.

Claim 7 has been amended to change the dependency from Claim 1 to claim 6, which recites the limitation of “the upper mesh flow distributor”. This amendment merely corrects a typographical error and does not alter the scope of the claim or add new matter. Entry of this amendment is respectfully requested.

Claim 16.

Claim 16 has been amended to delete the recitation of “the upper compression layer” on line 35 and to correctly recite “the upper mesh flow distributor”. This amendment merely corrects a typographical error and does not alter the scope of the claim or add new matter. Entry of this amendment is respectfully requested.

Claim 19.

Claim 19 has been amended to delete the recitation of “the microcolumn” and to correctly recite “the container”. This amendment merely corrects a typographical error and does not alter the scope of the claim or add new matter. Entry of this amendment is respectfully requested.

Claim 27.

Claim 27 has been amended to incorporate all of the limitations of Claim 26 which Claim 27 depends from. In addition, the phrase “the ratio of the diameter of the extraction media layer to the thickness of the extraction media layer being at least 10”. This limitation is found in the

specification, and in original Claim 16. Accordingly, these amendments do not add new matter. Entry of these amendments is respectfully requested.

Claim 28.

Claim 28 has been amended to correct a grammatical error. Accordingly, this amendment does not add new matter. Entry of this amendment is respectfully requested.

III. Claims 27 and 28.

The Office states in numbered paragraph 11 of the Office Action that Claims 27 and 28 would be allowable if rewritten to overcome the rejection(s) under 35 USC 112, 2nd paragraph, set forth in the Office action and to include all of the limitations of the base claim and any intervening claims.

The amendments to Claims 27 and 28 (which depends from Claim 27) (1) incorporates the limitations of Claim 26, from which claim 27 depends; and (2) quantifies the "thin layer" as "the ratio of the diameter of the extraction media layer to the thickness of the extraction media layer being at least 10". These amendments are believed to satisfy the Examiner's requirements, as stated in paragraph 11 of the Office Action, and place Claims 27 and 28 in condition for allowance. Such action is earnestly requested.

IV. Claim Objections.

Claims 1, 12, and 17 have been objected to as stated in numbered paragraph 1 of the Office Action. The amendments described above to Claims 1, 12, and 17 are believed to obviate the objection. Withdrawal of the objection is respectfully requested.

V. The Rejections Under 35 USC § 112, second paragraph.

Claims 7, 16, 19 and 26-28 have been rejected under 35 USC § 112, second paragraph for the reasons stated in numbered paragraph 3 of the Office Action. The cancellation of Claim 26 and the amendments described above to Claims 7, 16, 19 and 27 are believed to obviate this basis for rejection. Withdrawal of the rejection is respectfully requested.

VI. The Rejection Under 35 USC § 103(a).

Claims 1-5, 9-11, 17, 21, and 24-25 have been rejected under 35 USC § 103(a) as being unpatentable over Mehl (US Pat. No. 4,774,058) in view of Markell et al. (US Pat. No. 5,279,742) for the reasons stated in numbered paragraph 7 of the Office Action. Applicants

respectfully traverse this basis for rejection and request reconsideration of the rejection based on the following remarks.

A. There Is No Motivation To Combine The Cited References.

Applicants submit that the Office has not established a prima facie case of obviousness as there is no motivation, in the references themselves, or in the knowledge of the state of the art, to combine the references. Applicants request consideration of the following remarks and withdrawal of the rejection on this basis.

In forming a prima facie case of obviousness, the Office cites to Mehl (US Pat. No. 4,774,058) for teaching the limitations of Claims 1-5, 9-11, 17, 21, and 24-25. As admitted by the Office, Mehl does not teach the limitation that the particle size is less than 20 microns. The Office cites to Markell et al. (US Pat. No. 5,279,742) to remedy the deficiencies of Mehl, stating “[i]ncorporating particles having a size less than 20 microns in the extraction media of Mehl would have been obvious at the time the invention was made since such particles are known to be used for extraction process as taught in Markell et al.

Contrary to the assertion of the Office, Applicants submit that it would not be obvious to use particles having a size less than 20 microns in the extraction media. Mehl is silent as to the size of the separation media. The particles described in Markell are enmeshed in a PTFE fibril matrix. There is no teaching or suggestion in Markell et al. that microparticulate separation media, e.g., separation media having a diameter of less than 20 μm is suitable for use in a layer of separation media as claimed by Applicants. As described in the specification, it is known to use particulate silica as the solid media in a column (Specification , page 2, lines 36-37). However, as described in the attached Declaration of Thomas Good, a named inventor, and President and CEO of CERA, Inc., the assignee of the present Application, there is a great deal of difficulty in packing separation media having a diameter of less than 20 μm , into a microcolumn due to the consistency of microparticulate separation media. It was not until the inventors of the present invention produced the claimed extraction column that an extraction column having microparticulate separation media became a practical reality.

Accordingly, it is non-obvious to incorporate particles having a size less than 20 microns in the extraction media of Mehl. Although Markell teaches the use of such particles in an

extraction process, Markell teaches embedding the particles in a fibril matrix. It was generally thought, prior to Applicant's invention, that particles sized less than 20 microns were unsuitable for use in a layer of separation media as claimed by Applicants. Thus, there is no motivation in the references themselves, or the knowledge of those of skill in the art to combine the references. Applicants request withdrawal of the rejection and allowance of Claims 1-5, 9-11, 17, 21, and 24-25 on this basis.

B. The Commercial Success Of CERA's Products Establishes The Nonobviousness Of The Claimed Invention.

Applicants do not concede that the Office has established a *prima facie* case of obviousness. However, in support of the Applicant's position of the nonobviousness of the claimed invention, the Declaration of Thomas J. Good (the "Good Declaration") is submitted Under 35 U.S.C. § 1.132 herewith. Thomas J. Good is an inventor of the present Application and founder, President and CEO of CERA, Inc., the assignee of the present Application. The accompanying Good Declaration attests to the commercial success of CERA's products, manufactured according to the claimed invention (i.e., "CERA's products")

The Good Declaration establishes a nexus between the evidence of commercial success and the claimed invention and is probative evidence of the nonobviousness of the invention. In establishing a nexus between the commercial success and the claimed invention, the Good Declaration adequately defines CERA's product sales and attests that (i) the commercial success of CERA's products is commensurate in scope with the claimed invention; (ii) the commercial success of CERA's products is derived from the claimed invention; and (iii) the commercial success of CERA's products flows from the advantages disclosed in the Specification.

1. CERA's Sales Are Adequately Defined The Commercial Success Of CERA's Products Is Commensurate In Scope With The Claimed Invention And

As stated in the accompanying Good Declaration, over 5 million apparatus, manufactured according to the claimed invention, i.e., CERA's products, have been sold since their introduction in May of 1996. CERA is the only commercial producer of microcolumns having separation media with a diameter of less than 20 microns. CERA's products each have within the apparatus container (1) a passage having a thin layer of microparticulate extraction media

(less than 20 microns) for extracting a substance; and (2) upper and lower compression layers that press the extraction media therebetween. Accordingly, CERA's sales are adequately defined, and the products which have been sold correspond to the claimed invention.

2. The Commercial Success Of CERA's Products Is Derived From The Claimed Invention.

As also attested to in the Good Declaration, the commercial success of CERA's products is directly derived from the claimed invention. No extensive amount of advertising was conducted; CERA did not have a position as a market leader before the introduction of the claimed invention; CERA does not produce instrumentation that requires the use of the claimed invention or ties the consumer to the use of the claimed invention; and there are other competing products on the market that consumers are free to choose from. Thus, the commercial success enjoyed by CERA in selling their products is derived from the claimed invention. Utilizing the claimed features of the invention, CERA's extraction columns are able to obtain uniform flow of sample and eluent fluids through the extraction media. This results in high extraction yields with minimum elution volumes.

3. The Commercial Success Of CERA's Products Flows From The Advantages Disclosed In The Specification.

As also described in the Good Declaration, CERA's extraction columns are able to obtain advantages disclosed in the Specification, such as uniform flow of sample and eluent fluids through the extraction media. Further, CERA's products are inexpensive to use and manufacture, are stable during storage and transportation, and are compatible with existing automated equipment, further advantages described in the Specification. Due to the combination of the thin layer of microparticulate extraction media and the compression layers, rapid extraction of an analyte from a sample can be obtained, with sample volumes of less than .5 ml and eluent liquid volumes of around .5 to .75 ml. As stated in the Good Declaration, CERA's products satisfy a long-felt want and need for an inexpensive device that is capable of high extraction yields with minimum elution volumes. Because of these advantages, CERA's products have enjoyed substantial commercial success since their introduction and are expected to continue to do so.

The Good Declaration establishes a nexus between the commercial success of CERA's products and the claimed invention. The Commercial Success of CERA's products is strong probative evidence of the non-obviousness of the invention. Applicant's request that the Office consider the Commercial Success of CERA's product's as objective indica of non-obviousness and withdraw the rejection under 35 U.S.C. § 103(a).

VII. The Non-Statutory Double Patenting Rejection.

The Office has rejected Claims 1-8, 11-13, 21-22 and 25 on the ground of nonstatutory obviousness-type double patenting over claims 1, 4-7, 9-10, 12 and 14 of U.S. Patent No. 5,595,653 for the reasons stated in numbered paragraph 9 of the Office Action. The Office has also rejected Claims 9-10, 14-20 and 23-24 on the ground of nonstatutory obviousness-type double patenting over claims 1, 10, 15, 17 and 19 of U.S. Patent No. 5,595,653 in view of Pieper et al (US Pat. No. 5,391,298) for the reasons stated in numbered paragraph 10 of the Office Action.

In response to the nonstatutory double patenting rejections, upon withdrawal of the rejection under 35 USC §103(a) of the above-identified claims, Applicants will submit a terminal disclaimer, which Applicant's believe will overcome this basis for rejection.

CONCLUSION

The Applicant believes that all pending claims are in condition for allowance and such action is earnestly requested. If the present amendments and remarks do not place the Application in condition for allowance, the Examiner is encouraged to contact the undersigned, Applicant's representative, directly if there are any issues that can be resolved by telephone.

The Commissioner is authorized to charge the excess claim fees to Deposit Account No. 19-2090. The Commissioner is also authorized to charge \$60 for an extension for response within the first month. No other fees are believed due with this Response. However, if any fees are due, the Commissioner is authorized to charge any such fees to Deposit Account No. 19-2090.

Respectfully Submitted,
SHELDON & MAK PC

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